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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,399	01/19/2001	Wesley B. Bruce	1165	7368

27310 7590 05/01/2003

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/766,399

Applicant(s)

BRUCE ET AL.

Examiner

Juliet C. Switzer

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2-16.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

JEFFREY FREDMAN  
PRIMARY EXAMINER

Continuation of 2. NOTE: The amendments will not be entered because they raise the issue of new matter which would require further consideration under 112 1st paragraph. As such, they do not place the application in better form for appeal. .

Continuation of 5. does NOT place the application in condition for allowance because:

The request for reconsideration largely refers to the amended claims. Since the amendment to the claims will not be entered, many of the remarks are moot. Nonetheless, the remarks are addressed insofar as they are relevant to the pending claims.

Applicant argues that in view of the decision *In re Angstadt*, the specification is required to provide sufficient enablement so that one skilled in the art could make the embodiments encompassed by the claims. However, this is not entirely accurate, because the statute (112 1st) clearly requires enablement to make and use the claimed invention. Nonetheless, it is also significant to note that the examiner has rejected the claims because they have large breadth, only single example is provided within the claimed genus, and the subject area is highly unpredictable, for all of the reasons discussed herein and in the rejections. This situation differs tremendously from *In re Angstadt*, wherein a large number (forty) examples were provided, only one of which did not work. In this case, the court determined that there was sufficient guidance in an unpredictable art. The court further stated, however, that "each case must be determined by its own facts." In this case, for the reasons discussed herein and in the final office action, the rejection is maintained.

Applicant further argues that it would be "well known to one of skill in the art the process of analyzing sequences to determine which had 90% identity," however, this argument overlooks the issues of the rejection entirely. The issue is not whether one could actually make and use the invention as claimed. While one skilled in the art could identify sequences that have 90% homology to the disclosed sequences, it is entirely unpredictable as to which ones of these hundreds of thousands of possible sequences would actually be functional promoters.

Applicant states at page 9 of the remarks that the claims do not encompass nucleotide sequence with promoter elements that are not arranged in the claimed sequential order, however section (c) of the independent claim encompasses promoters that have elements in any order, provided a portion of the promoter hybridizes the promoter of section (a) or (b)

Applicant cites the WANDS factors, and it is noted that it is precisely these factors that are analyzed in the FINAL rejection. Considering all of these factors, especially the breadth of the claims, the unpredictability in the prior art, the lack of guidance as to how the disclosed working promoters can be modified yet remain function, that led the examiner to the conclusion that undue experimentation is necessary to practice the claimed invention. The rejection is maintained for these reasons and the reasons of record.